IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	CIVIL ACTION NO. 99-20593
v.	)	
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8972

Bartle, J. November 21, 2012

Norma Mudd ("Ms. Mudd" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[2]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with

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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In December, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Anita M. Arnold, D.O. Based on an echocardiogram dated April 11, 2002, Dr. Arnold attested in Part II of claimant's Green Form that Ms. Mudd suffered from moderate mitral regurgitation, an abnormal left ventricular end-systolic dimension, and a reduced ejection fraction in the range of 50% to 60%.[3] Based on such findings,

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2. (...continued)
serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

3. Dr. Arnold also attested that Ms. Mudd had moderate aortic regurgitation and New York Heart Association Functional Class I symptoms. These conditions are not at issue in this claim.

claimant would be entitled to Matrix A-1,[4] Level II benefits in the amount of $538,973.[5]

In the report of claimant's echocardiogram, Dr. Arnold stated that claimant had "moderate mitral insufficiency." Dr. Arnold, however, did not specify a percentage as to the level of claimant's mitral regurgitation. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In June, 2005, the Trust forwarded the claim for review by Robert L. Gillespie, M.D., F.A.C.C., F.A.S.E., one of its auditing cardiologists. In audit, Dr. Gillespie concluded that there was no reasonable medical basis for the attesting physician's finding that Ms. Mudd had moderate mitral regurgitation because her echocardiogram demonstrated only mild

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4. Although Dr. Arnold attested that Ms. Mudd suffered from mitral annular calcification, the presence of which requires the payment of reduced Matrix Benefits, see Settlement Agreement § IV.B.2.d.(2)(c)ii)d), the auditing cardiologist found no reasonable medical basis for that finding. Given our disposition, we need not determine this issue.

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of a reduced ejection fraction, which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

mitral regurgitation. In support of this conclusion, Dr. Gillespie explained that claimant's "RJA/LAA ratio is 10-15% in multiple views. Never is it 20% or more."

Based on the auditing cardiologist's finding that claimant had mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. Mudd's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[6] In contest, claimant submitted a letter from Ira R. Friedlander, M.D., F.A.C.C., who agreed with the attesting physician that claimant had moderate mitral regurgitation. Specifically, Dr. Friedlander stated that:

> By the criteria established of 20% to 40% RJA/LAA the [claimant] has moderate regurgitation. This is observable in parasternal long and short axis views as well as in the apical four and two chamber views. Some of the frames are brief but without question visible and measurable when the tape is reviewed slowly and carefully. Most measurements of RJA/LAA are in the range of 25 to 30%.

Claimant also argued that the attesting physician's finding of moderate mitral regurgitation was supported by the findings of five (5) additional echocardiograms, including the echocardiogram

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6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Mudd's claim.

performed through the Trust's Screening Program.[7] Finally, Ms. Mudd asserted that the auditing cardiologist improperly limited his review to one parasternal view.

The Trust then issued a final post-audit determination, again denying Ms. Mudd's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Mudd's claim should be paid. On January 19, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5953 (Jan. 19, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on April 6, 2006, and claimant submitted a sur-reply on April 27, 2006. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[8] to review claims after the Trust and

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7. See Settlement Agreement § IV.A.1.a. (Screening Program established under the Settlement Agreement).

8. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance (continued...)

claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Sandra V. Abramson, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Mudd argues that she has established a reasonable medical basis for her claim because two Board-Certified cardiologists independently agreed that she had moderate mitral regurgitation. In addition, claimant contends

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8. (...continued)
of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

that the concept of inter-reader variability accounts for the differences between the opinions provided by claimant's physicians and the auditing cardiologist, Dr. Gillespie. According to claimant, there is an "absolute" inter-reader variability of 15% when evaluating mitral regurgitation. Thus, Ms. Mudd contends that if the Trust's auditing cardiologist or a Technical Advisor concludes that the RJA/LAA ratio for a claimant is 5%, a finding of a 20% RJA/LAA ratio by an attesting physician is medically reasonable.

In response, the Trust argues that claimant has failed to establish a reasonable medical basis for her claim and that "Dr. Friedlander does not and cannot identify any sustained regurgitant jet seen in multiple consecutive frames and multiple cycles on [claimant's] echocardiogram which fill at least 20% of a representative left atrium." The Trust further asserts that inter-reader variability does not establish a reasonable medical basis for the claim because Dr. Gillespie specifically determined that claimant's "RJA/LAA ratio never exceeds 15% and further concluded that there is no reasonable medical basis for Dr. Arnold's Green Form representation of moderate mitral regurgitation."

The Technical Advisor, Dr. Abramson, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation. Specifically, Dr. Abramson found that:

> In reviewing the transthoracic echocardiogram from 4/11/02, my visual estimate is that there is only mild mitral regurgitation in the parasternal views and the apical views. I measured the mitral regurgitant jet and the left atrial area (in the same frame) in five representative cardiac cycles. My measurements for mitral regurgitant jet area/left atrial area are $3.0cm^2/21.1cm^2$, $2.8cm^2/18.7cm^2$, $3.1cm^2/19.3cm^2$, $2.8cm^2/18.0cm^2$ and $2.7cm^2/18.5cm^2$. These ratios are 14%, 15%, 16%, 16% and 15%, all of which are considerably less than 20%, and are consistent with mild mitral regurgitation. There are no measurements on the tape for me to critique.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, claimant does not refute the specific conclusions of the auditing cardiologist or the Technical Advisor. Ms. Mudd does not adequately rebut the auditing cardiologist's determination that the "RJA/LAA ratio is 10-15% in multiple views. Never is it 20% or more." Nor does she challenge the Technical Advisor's conclusion that claimant's RJA/LAA ratios are "14%, 15%, 16%, 16% and 15%, all of which are considerably less than 20%, and are consistent with mild mitral regurgitation."[9] Although claimant submitted a letter from an additional cardiologist, neither claimant nor her physicians identified any particular error in the conclusions of the auditing cardiologist and the Technical Advisor. Mere disagreement with the auditing cardiologist or the Technical

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9. Despite an opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34.

Advisor without identifying any specific errors by them is insufficient to meet a claimant's burden of proof.

Claimant's reliance on inter-reader variability to establish a reasonable medical basis for the attesting physician's representation of moderate mitral regurgitation also is misplaced. The concept of inter-reader variability already is encompassed in the reasonable medical basis standard applicable to claims under the Settlement Agreement. In this instance, the attesting physician's opinion cannot be medically reasonable where the auditing cardiologist determined that the echocardiogram shows RJA/LAA ratios of 10% to 15% and the Technical Advisor concluded that claimant's echocardiogram demonstrates RJA/LAA ratios of 14% to 16%. Adopting claimant's argument that inter-reader variability expands the range of moderate mitral regurgitation by ±15% would allow a claimant to recover Matrix Benefits with an RJA/LAA ratio as low as 5%. This result would render meaningless this critical provision of the Settlement Agreement.[10]

Finally, we reject claimant's assertion that she is entitled to Matrix Benefits because an echocardiogram conducted in the Screening Program for Fund A Benefits under the Settlement Agreement demonstrates moderate mitral regurgitation. See

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10. Moreover, the Technical Advisor took into account the concept of inter-reader variability as reflected in her statement that "it would be impossible for a reasonable echocardiographer to interpret this severity of mitral regurgitation as moderate even taking into account inter-reader variability."

Settlement Agreement § IV.A. The Settlement Agreement clearly provides that the sole benefit that an eligible class member is entitled to receive based on an echocardiogram performed in the Screening Program is a limited amount of medical services or a limited cash payment:

> All Diet Drug Recipients in Subclass 2(b) and those Diet Drug Recipients in Subclass 1(b) who have been diagnosed by a Qualified Physician as FDA Positive by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period, will be entitled to receive, at the Class Member's election, either (i) valve-related medical services up to $10,000 in value to be provided by the Trust; or (ii) $6,000 in cash.

Id. § IV.A.1.c. Thus, by the plain terms of the Settlement Agreement, a Screening Program echocardiogram does not automatically entitle a claimant to Matrix Benefits.

Indeed, this conclusion is confirmed by the Settlement Agreement provisions concerning claimants eligible for Matrix Benefits. Specifically, claimants receiving a diagnosis of FDA Positive or mild mitral regurgitation merely become eligible to seek Matrix Benefits. See id. § IV.B.1. Further, adopting claimant's position would be inconsistent with Section VI.E. of the Settlement Agreement, which governs the audit of claims for Matrix Benefits, as well as this Court's decision in PTO No. 2662 (Nov. 26, 2002), which mandated a 100% audit for all claims for Matrix Benefits. As nothing in the Settlement Agreement supports the conclusion that a favorable Screening Program echocardiogram for purposes of Fund A Benefits results in an immediate

entitlement to Matrix Benefits, we decline claimant's request to interpret the Settlement Agreement in this fashion.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we affirm the Trust's denial of Ms. Mudd's claim for Matrix Benefits.